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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/894,018

06/27/2001

Alessandro Sette

2060.0320003

7107

50710

7590

12/14/2007

STERNE, KESSLER, GOLDSTEIN & FOX, P.L.L.C.  
1100 NEW YORK AVE.  
WASHINGTON, DC 20005

EXAMINER

ALLEN, MARIANNE P

ART UNIT

PAPER NUMBER

1647

MAIL DATE

DELIVERY MODE

12/14/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/894,018	<b>Applicant(s)</b> SETTE ET AL.	
	<b>Examiner</b> Marianne P. Allen	<b>Art Unit</b> 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 September 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 27-32, 34, 36, 62, 63, 65-73, 77, 78 and 81-83 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 27-32, 34, 36, 65-73, 81-83 is/are allowed.
- 6) ☒ Claim(s) 62, 63, 77 and 78 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/17/07 has been entered.

Applicant's arguments filed 9/17/07 have been fully considered but they are not fully persuasive.

Claims 27-32, 34, 36, 62-63, 65-73, 77-78, and 81-83 are under consideration by the examiner.

The rejection of claims 28-29, 63, 73, and 78 under 35 U.S.C. 102(e) as being anticipated by Sette et al. (U.S. Patent No. 6,689,363 B1) is withdrawn in view of applicant's amendment.

#### ***Claim Rejections - 35 USC § 112***

Claims 62-63 and 77-78 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 62 is directed to designing a polypeptide having 10 or more CTL epitopes and 2 or more HTL epitopes.

Claim 63 is directed to designing a polypeptide having 5 or more HTL epitopes and 2 or more CTL epitopes.

Claim 77 is directed to designing a polynucleotide encoding 5 or more CTL epitopes and 2 or more HTL epitopes.

Claim 78 is directed to designing a polynucleotide encoding 5 or more HTL epitopes and 2 or more CTL epitopes.

These are not originally filed claims and these claims have been amended several times. Applicant has pointed to various points in the specification in support for these claims. None of the places pointed to provides support or contemplates constructs with these combinations of HTL and CTL epitopes.

Applicant's arguments are not persuasive. While *ipsis verbis* support is not required, a fair reading of the originally filed specification must convey that these generic constructs were contemplated as being the invention. No portion of the specification sets forth the concepts set forth in claims 62-63 and 77-78. Applicant's arguments with respect to *Kao v. Unilever*, 441 F.3d. 963,968 (Fed. Cir. 2006) are not germane. The positive action or step to perform is not at issue in this application (i.e. how to make the construct). The issue is what construct does the specification contemplate making. The claimed numbers of CTL and HTL epitopes required to be included are not a step that is "so straightforward" in the context of *Kao v. Unilever*. This decision concerned a method for removing keratotic plugs from skin with a cosmetic article by wetting the skin or said cosmetic article; applying onto the skin said cosmetic article; and peeling off said cosmetic article after drying. The written description issue in this decision concerned the positive action or step to perform not the identity of what to apply.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is 571-272-0712. The examiner can normally be reached on Monday-Friday, 5:30 am - 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Marianne P. Allen/  
Primary Examiner, Art Unit 1647

mpa